REMARKS

The Office Action of December 6, 2007, has been carefully considered.

Claims 79, 82, 84, 87, 92, 95, 97, 98 and 99 have been rejected under 35 USC 103(a) over Hirai et al. in view of Kurihara et al., Kano et al., and Mehlem.

It is Applicants' continuing position that none of the references, taken alone or in combination with each other, disclose or suggest the present invention.

> To establish a *prima facie* case of obviousness, three **basic** criteria must be met. First there must be some **suggestion or motivation**, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must **be a reasonable expectation of success.** Finally, the prior art reference (or references when combined) must teach **all the claim limitations.** (M.P.E.P. 2143).

Clearly, Hirai et al. fails to make obvious the claimed invention.

Hirai et al. relates to a preparation form for non-oral and non-injection administration that is conducive to an improved bioavailability of a hydrophilic or water-soluble drug that is poorly absorbable through the gastrointestinal tract (col. 1, lines 19-25). More particularly, Hirai et al. found that when such a drug is used by non-oral and non-injection administration in combination with cyclodextrin, the

absorption of the drug is markedly increased (col. 1, lines 25-29).

Significantly, the Hirai et al. reference says nothing about using α-cyclodextrin to enhance the biological activity of an LH-RH peptide analogue when the drug is administered orally.

Indeed, reliance on the Hirai et al. reference indicates that the Patent Office considers the enhancement of the biological activity of a drug and the increase in absorption of a drug to be equivalent events, which clearly they are not.

Moreover, since the Hirai et al. reference discloses a composition and method for increasing the bioavailability of a hydrophilic or water-soluble drug that is poorly absorbable through the gastrointestinal tract, there is no motivation to modify the disclosed method of nasal, vaginal, or rectal administration of an LH-RH peptide analogue.

The Kurihara et al. reference does not fill the gaps left by Hirai et al.

Kurihara et al. teaches that cyclodextrin may be used to improve the solubility of cyclosporins. However, the reference also fails to disclose or suggest that α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when the drug is administered orally in combination with α-cyclodextrin.

The Mehlem reference also does not fill the gaps left by Hirai et al. and Kurihara et al.

Mehlem discloses a pharmaceutical composition containing "Peptichemio" a complex series of peptides containing m-L-sarcolysine, and a cyclodextrin carrier that serve to regulate the bioavailability of Peptichemio. The Peptichemio peptides are specific oligopeptides having from 3 to 5 amino acids and are useful as chemotherapeutic agents in cancer therapy ([0002] to [0008].

There is no mention or suggestion in Mehlem that α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when the drug is administered orally in combination with α-cyclodextrin.

The Kano et al. reference also does not fill the gaps left by Hirai et al., Kurihara et al., and Mehlem.

The Kano et al. reference relates to a mechanism for binding to the flexible cavity of permethylated α-cyclodextrin. Again, there is no disclosure or suggestion in Kano et al. that α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when the drug is administered orally in combination with α-cyclodextrin.

For the reasons stated above, the Hirai et al., Kurihara et al., Kano et al., and Mehlem references do not teach or suggest the invention defined by the present claims.

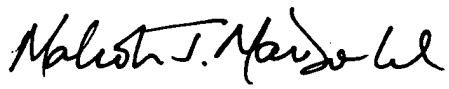
Accordingly, the rejection under 35 U.S.C. 103(a) should be withdrawn.

In view of the deficiencies in the art, claims 79, 82, 84, 87, 92, 95, 97, 98 and 99 are not *prima facie* obvious to one of ordinary skill in the art and, accordingly, withdrawal of the rejection under 35 U.S.C. 103(a) with respect to these claims is respectfully requested.

Applicants submit that the present application is now in condition for allowance and early notice of such action is earnestly solicited. If any final points remain that can be clarified by telephone, Examiner Desai is respectfully encouraged to contact Applicants' attorney at the number indicated below.

Applicants hereby petition the Commissioner for Patents to extend the time for reply to the notice dated December 6, 2007 for three (3) months from March 6, 2008, to June 6, 2008. A duly completed credit card authorization form is attached to effect payment of the extension fee.

Respectfully submitted



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